

REMARKS

Reexamination of this application is respectfully requested.

Applicants thank the Examiner for pointing out that the preliminary amendment filed May 8, 2002, contained two claims with the number 26. Applicants have renumbered the claims as 1-34 in the listing of claims provided herein, with the second claim 26 as claim 27. See Office Action at Page 2.

The listing of claims presented herein amends claims 1, 2, 5 and 8 without prejudice to or disclaimer of previously claimed subject matter, and adds new claims 35-39. With entry of this amendment, claims 1-37 are pending in this application.

Support for the amendment of claims 1, 2 and 8 is found in original claims 1, 2 and 8, and at page 1, lines 3-5.

Claim 5 has been amended to make the claim clearer, without changing its scope.

New claims 35 and 36 find support in original claims 9 and 10.

New claim 37 finds support in original claims 1 and claim 8; and at page 3, lines 20-38; page 4, line 1 to page 5, line 27; page 6, lines 27-35; page 11, lines 1-6; and page 13, lines 31-35.

New claims 38 and 39 find support at page 1, lines 3-5 and page 5, lines 7-27.

The amendments to the claims are supported by the specification as filed and do not add new matter to the application. Accordingly, Applicants submit that entry of this Amendment is proper.

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Rejection Under 35 U.S.C. § 112, second paragraph

The Office rejected claim 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The basis for this rejection was the Office's contention that the term "type," which appears in claim 5, is indefinite. Applicants have amended claim 5 to remove the word "type". This amendment renders this rejection moot. Accordingly, Applicants respectfully request that the Office withdraw the rejection.

Rejection for Obviousness-Type Double Patenting

The Office rejected claims 1-12, 17 and 18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,183,783 (the "783 patent"). The Office notes that the allegedly conflicting claims are not identical, but contends that they are nonetheless not patentably distinct from each other. Specifically, the Office asserts that the particle sizes recited in the instant claims are "deemed to be included in the generic composition claims in [the '783] patent. Applicants respectfully traverse.

"[T]he analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection. . ." M.P.E.P. 804(II)(B)(1). During examination, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness under § 103(a). M.P.E.P. 2142. Until the Examiner establishes a *prima facie* case, Applicants are under no obligation to submit evidence of nonobviousness. *Id.* To establish a *prima facie* case on the basis of a single reference,

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the Examiner must show, *inter alia*, that the reference teaches or suggests every limitation of the rejected claims. *Id.* The Examiner has not met this burden.

Applicants' claims are directed to biocompatible microparticles for inhalation, having a mean diameter of between 1 and 30 μm . In contrast, the claims of the '783 patent recite microcapsules and methods of preparing microcapsules, where the microcapsules have a mean diameter between 10 nm and 1 mm, or between 20 nm and 50 μm . The '783 patent does not indicate that any of these microcapsules are suitable for inhalation. The '783 patent also fails to provide any other suggestion to one of skill to select microcapsules between 1 to 30 μm for any reason, from among the genus of microcapsules claimed in the '783 patent.

The Examiner's observation, that microcapsules of 1 to 30 μm diameter are within the range of microcapsules of 10 nm to 1 mm diameter or 20 nm to 50 μm diameter, fails to point to any teaching or suggestion to make microcapsules between 1 to 30 μm diameter, for inhalation or any other purpose. Accordingly, the Examiner has failed to make out a *prima facie* case of obviousness of claims 1-12, 17 and 18 over claims 1-20 of the '783 patent. Thus, the Examiner has failed to show that claims 1-12, 17, and 18 are unpatentable to Applicants' under the judicially created doctrine of obviousness-type double patenting. In view of these circumstances, Applicants respectfully request that the rejection of claims 1-12, 17 and 18 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

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Rejections Under 35 U.S.C. § 102(b)

The Office rejected claims 1-8, 11-14, 16-21, 25, 27, 31, 32 and 34 under 35 U.S.C. § 102(b), as being anticipated by WO 98/31346 (the “346 application”). According to the Office, the ‘346 application discloses polymeric microparticles for inhalation. Without pointing to any specific passages in the ‘346 application, the Office contends that the reference discloses embodiments within Applicants’ claims. Applicants respectfully traverse.

The Office states that the particles disclosed in the ‘346 application are coated with a surfactant. The inventors have informed the undersigned that the particles disclosed in the ‘346 application are, however, structurally distinct from the microparticles of Applicants’ claims. In one embodiment, the ‘346 application particles include only a therapeutic agent in a complex with another charged molecule (page 6, lines 17-19). In a second embodiment, the particles include only a therapeutic agent and a surfactant (page 6, lines 19-21). And in a third embodiment, the particles include a surfactant and charged molecules forming a complex (page 6, lines 21-22). According to the ‘346 application, the surfactant may be incorporated throughout the particles and on the surface during particle formation (page 12, lines 11-14), or the surfactant may be coated on the particles after the particles are formed (page 12, lines 13-14). Methods for coating the surfactant on the particles include surface adsorption, ionic or covalent attachment, or physically “entrapping” within a surrounding matrix (page 12, lines 14-16).

The inventors believe that the particles described in the ‘346 application are matricial microspheres. Further, the only methods of making the particles that are

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provided in the '346 application require a process wherein the active material is dissolved in an organic solvent or in aqueous phase. This necessarily leads to the production of a matricial microsphere, which is structurally distinct from the microspheres of Applicants' claims.

The microparticles of the present invention comprise a core containing the active principle, which can be coated with a layer of coating agent deposited by the supercritical fluid technique (Application at page 4, line 35 to page 5, line 5). Each particle is coated with the coating agent. Thus, the particles do not aggregate in a matrix of coating agent. As described in the application, these microparticles can be obtained from a suspension of active principles, which are not in a dissolved form. (Page 6, lines 27-35; page 11, lines 1-6.)

In view of these circumstances, Applicants respectfully request that the rejection for anticipation over the '346 application be withdrawn.

The Office also rejected claims 1-8, 10-13, 17-19, 24, 30 and 31 under 35 U.S.C. § 102(b), as being anticipated by EP 0 706 821 ("EP '821"). The inventors emphasize that EP '821, like the '346 application, describes particles of matricial structure. For example, the particles are described at col. 2, lines 49-53, as "compris[ing] an active substance conformationally entrapped within a layer of a coating substance having a thickness ramping from . . ." In view of these circumstances, Applicants respectfully request that the rejection for anticipation over EP '821 be withdrawn.

The Office also rejected claims 1-12, 17 and 18 under 35 U.S.C. § 102(b), as being anticipated by FR 2 753 639 ("FR '639"). Because FR '639 is published in French, this rejection is based on the disclosure of the '783 patent, which claims priority

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to FR 96 11665, which published as FR '639. Applicants' claims are directed to biocompatible microparticles for inhalation having a mean diameter of between 1 and 30 μm . In contrast, the '783 patent discloses microcapsules having a mean diameter between 10 nm and 1 mm (col. 6, lines 48-50.).

The '783 patent also discloses three subgenera of microcapsules within the incredibly broad 10 nm to 1 mm genus. First, as noted by the Examiner (Office Action at page 5), a subgenus of microcapsules of 20 nm to 500 μm diameter is disclosed (col. 6, lines 48-50.) Second, Example 1 discloses a subgenus of microcapsules of 200-300 μm diameter. Finally, Example 9 discloses a subgenus of microcapsules of 50 μm diameter (col. 8, lines 50-53.). The first subgenus, like the whole genus, encompasses a much broader spectrum of microcapsule sizes than Applicants' claims. The latter two subgenera are much narrower. However, not a single microcapsule of either subgenus is within the size range in Applicants' claims.

Where, as here, a prior art reference discloses a range that overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. (M.P.E.P. 2131.03.) The critical question is whether the claimed subject matter is disclosed with sufficient specificity to constitute an anticipation. (*Id.*) The '783 patent fails this test. One of skill in the art reading the '783 patent would have no reason to envisage microparticles of between 1 to 30 μm diameter, as required by Applicants' claims. In view of these circumstances, Applicants respectfully request that the rejection for anticipation over FR '639 be withdrawn.

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Finally, claims 9 and 10 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/29998 (the “998 application”). Claims 9 and 10 are process claims, and require suspending an active principle in a solution (claim 9) or a supercritical fluid (claim 10). In contrast, in the processes disclosed in the ‘998 application, the active principle is dissolved in a solution. (See, e.g., Example 1.) This is not the same as suspension, as in Applicants’ claims. Absent a disclosure of suspension, the ‘998 application does not disclose each element of claims 9 or 10, and for this reason can not anticipate these claims. In view of these circumstances, Applicants respectfully request that the rejection for anticipation over the ‘998 application be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Office rejected claims 15, 19, 20, 22, 23, 25, 26, 28, 29 and 33 under 35 U.S.C. § 103(a), as being obvious over the ‘346 application. The basis for this rejection is the Office’s contention that the species recited in these claims, though not anticipated by the ‘346 application, are rendered obvious by the ‘346 application, in view of the level of ordinary skill in the art. However, as described by the inventors, the particles described in the ‘346 application are matricial microspheres. In contrast, the microparticles of the present invention comprise a core containing the active principle, which can be coated with a layer of coating agent deposited by the supercritical fluid technique (Application at page 4, line 35 to page 5, line 5). Each particle is coated with the coating agent. The Office has provided nothing to suggest how the matricial microspheres of the ‘346 application would be modified by one of skill, absent

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Applicants' teachings, to arrive at the microspheres of Applicants' claims. Accordingly, the Office has not made out a *prima facie* case of obviousness. In view of these circumstances, Applicants respectfully request that the rejection for obviousness over the '346 application be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims 1-39.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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